



MAY 26 2006

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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,826,868

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,826,868, which claims the animal drug product ZUBRIN® (tepoxalin) and methods of its use, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,404 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,404 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of July 28, 2005 (70 Fed. Reg. 43701). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase) + Approval Phase} \\ &= \frac{1}{2} (1,887 \text{ days}) + 460 \text{ days} \\ &= 1,404 \text{ days (3.8 years)}\end{aligned}$$

Since the regulatory review period began October 28, 1996, after the patent issued (May 2, 1989), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,826,868
Granted:	May 2, 1989
Original Expiration Date ¹ :	May 29, 2006
Applicant:	Michael P. Wachter et al.
Owner of Record:	Ortho Pharmaceutical Corporation

¹Subject to the provisions of 35 U.S.C. § 41(b).

Title: 1,5-DIARYL-3-SUBSTITUTED PYRAZOLES
PHARMACEUTICAL COMPOSITIONS AND USE

Product Trade Name: ZUBRIN®

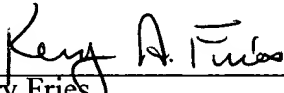
Term Extended: 1,404 days

Expiration Date of Extension: April 2, 2010

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext. By FAX: (571) 273-7755
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755 or by email to mary.till@uspto.gov.



Kery Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
5600 Fishers Lane
Rockville, MD 20857

RE: ZUBRIN®
FDA Docket No.: 03E-0410

Attention: Beverly Friedman